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| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371 | | ATTORNEY'S DOCKET NUMBER 532552000102 |
| INTERNATIONAL APPLICATION NO. PCT/US2004/011812 | INTERNATIONAL FILING DATE 16 April 2004 | U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/553,373 |
| TITLE OF INVENTION COMPOSITIONS FOR DELIVERY OF DRUG COMBINATIONS | | PRIORITY DATE CLAIMED 16 April 2003 |
| APPLICANT(S) FOR DO/EO/US Paul TARDI et al. | | |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: | | |
| 1. <input type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. | | |
| 2. <input checked="" type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. | | |
| 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. | | |
| 4. <input type="checkbox"/> The US has been elected (Article 31). | | |
| 5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) | | |
| a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). | | |
| b. <input type="checkbox"/> has been communicated by the International Bureau. | | |
| c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). | | |
| 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). | | |
| a. <input type="checkbox"/> is attached hereto. | | |
| b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). | | |
| 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) | | |
| a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). | | |
| b. <input type="checkbox"/> have been communicated by the International Bureau. | | |
| c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. | | |
| d. <input type="checkbox"/> have not been made and will not be made. | | |
| 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). | | |
| 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). | | |
| 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). | | |
| Items 11 to 20 below concern document(s) or information included: | | |
| 11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. (3 pages) | | |
| 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. | | |
| 13. <input type="checkbox"/> A preliminary amendment. | | |
| 14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76. | | |
| 15. <input type="checkbox"/> A substitute specification. | | |
| 16. <input type="checkbox"/> A power of attorney and/or change of address letter. | | |
| 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825. | | |
| 18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). | | |
| 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). | | |

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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| 20. <input checked="" type="checkbox"/> Other items or information: <div style="margin-left: 150px;">PTO/SB/08a/b Form (3 pages plus duplicate) References (34) Return Receipt Postcard</div> | | | |
| The following fees have been submitted | | CALCULATIONS | PTO USE ONLY |
| 21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)) \$300 | | \$ | |
| 22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 All other situations \$200 | | \$ | |
| 23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB \$400 All other situations \$500 | | \$ | |
| TOTAL OF 21, 22 and 23 = | | \$ 0.00 | |
| <input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof. | | | |
| Total Sheets | Extra Sheets | Number of each additional 50 or fraction thereof (round up to a whole number) | RATE |
| - 100 = | /50 = | | x \$250.00 |
| | | \$ | |
| Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)). | | \$ | |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE |
| Total claims | - 20 = | | x |
| Independent claims | - 3 = | | x |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable) | | + | 360.00 |
| TOTAL OF ABOVE CALCULATIONS = | | \$ 0.00 | |
| <input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/3. | | 0.00 | |
| SUBTOTAL = | | \$ 0.00 | |
| Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). | | \$ | |
| TOTAL NATIONAL FEE = | | \$ 0.00 | |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property | | \$ | |
| TOTAL FEES ENCLOSED = | | \$ 0.00 | |
| | | Amount to be refunded: | \$ |
| | | Amount to be charged | \$ |

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☐ A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ 0.00 to cover the above fees.
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 03-1952. ~~A duplicate copy of this sheet is enclosed.~~
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

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CUSTOMER NUMBER: 25225



SIGNATURE

Kate H. Murashige
NAME

29,959
REGISTRATION NUMBER

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)
10/553,373

INTERNATIONAL APPLICATION NO.
PCT/US2004/011812

ATTORNEY'S DOCKET NUMBER
532552000102

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: MS PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: December 16, 2005Signature:  (Lenay Rogus)